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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,330	06/23/2003	Clarence Nathaniel Ahlem	202.2D2	9052

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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,330

Applicant(s)

AHLEM ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 and 50-79 is/are pending in the application.
- 4a) Of the above claim(s) 25-28, 57, 58 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 50-56, 58, 60-74 and 76-79 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/05</u> . | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 25-28 and 50-79 are pending in the present application. Claims 25-28, 57, 59 and 75 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 50-56, 58, 60-74 and 76-79 stand rejected as indicated below.

Double Patenting

3. **The provisional rejection of claims 29-34, 36, 39 and 40 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/651,515 is made moot by the cancellation of the instant claims.**
4. Claims 50-56, 58, 60-74 and 76-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 9-11 of copending Application No. 10/651,515.

The claims stand rejected for the reasons given in the previous Office Action (see paragraph #5 of the previous Office Action).

The examiner notes applicant comment that the rejection will be addressed once patentable subject matter is identified.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 50-56, 58, 60-74 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating innate immune suppression due to radiation therapy, does not reasonably provide enablement for preventing innate immune suppression due to radiation therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claim contemplates the use of the claimed compounds in the prevention of innate immune suppression condition due to irradiation. The present specification lacks guidance and/or working examples of prevention of the claimed condition. In addition, there is no known method(s) for the determination of a person susceptible to said disorder and, thus, in need of preventive treatment. Thus, in order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would have to search the prior art to find, if possible, a model for determining a person prone to innate immune suppression as defined by the present specification and, thus, in need of preventive treatment. The amount of experimentation

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necessary to make said determination is undue because of the lack of guidance and/or working example in the present specification.

7: Claims 50-56, 58, 60-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite the administration (a) of about 4-40 mg/kg/day of the claimed compound to a non-human primate and/or (b) for 7 consecutive days (see claim 65). The present specification lacks disclosure of said limitations and, thus, does not convey to the skilled artisan in the art, that at the time the application was filed, had possession of the instantly claimed invention.

The examiner notes that no support was found in the sections of the present specification cited by applicant.

Claim Rejections - 35 USC § 102

8. The rejection of claims 29-34, 36, 39 and 40 under 35 USC 102(b) over Loria (US 5,461,042) is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 50-56, 58, 60-74 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loria (US 5,461,042).

Loria teaches the use of steroid derivatives such as 3 β ,17 β -dihydroxyandrost-5-ene (androstenediol) in ameliorating the adverse effects of radiation therapy (see the entire article, especially col. 4, lines 16-35 and claims 1 and 3).

Claims 50-56, 58 and 60-66 differ from the reference by reciting the administration of specific amounts of the prior art compound.

Claims 63-65, 67-74 and 76-79 differ by reciting specific treatment regimens.

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However, Loria teaches (a) dosages used will depend on the size and condition of the host as well as the route of administration and (b) a preferred dose range of 0.2-30 mg/day (see col. 17, lines 38-47). In addition, the determination of dosages and/or treatment regimen are routine in the medical art and, thus, well within the level of skill of the ordinary artisan in the art. Therefore, the claimed dosages and/or treatment regimen are prima facie obvious in view of the cited prior art and the level of skill of the ordinary artisan in the art at the time of the present invention absence a showing of criticality.

Response to Arguments

11. Applicant's arguments filed September 21, 2005 have been fully considered but they are not persuasive.

Applicant argument is that the cited prior art does not (a) expressly or inherently disclose any weight in terms of kg and, thus, they cannot disclose any dose in terms of mg/kg/day and (b) disclose any specified time period for dosing.

As indicated above in #10, the determination of dosages and/or treatment regimen is routine in the medical art and, thus, the recitation of a known treatment protocol in terms of dosages and/or treatment regimen is not patentability absence a showing of criticality. See for example, In re Russell, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

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Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

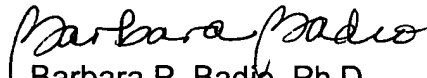
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badro, Ph.D.
Primary Examiner
Art Unit 1617

BB
December 7, 2005